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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,445	05/23/2006	Jonathan Hughes	BT/3-22348/A/PCT	4198

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EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
04/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/580,445	HUGHES ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-11* is/are pending in the application.

4a) Of the above claim(s) *2,5 and 9-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 4* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3, 4 and 8 as amended (1/07/2009) are under examination in the instant office action.

This application contains claims drawn to nonelected invention(s) in the reply filed on 6/20/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Deposit

Deposit requirement for strain *Dietzia natronolimnaious* NCIMB 41165 has been met in the papers filed 1/07/2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3 and 4 as amended remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. (IDS reference; Biosci. Biotech. Biochem., 1996, 60(9):1391-1400), Nagasawa et al. (IDS reference; Pure and Appl. Chem. 1995, 67(7):1241-1256), US 6,562,603 (Bramucci et al) and US 6,916,638(Aoki et al).

Claims are directed to a method for producing ethylenically unsaturated amide wherein the method comprises one active step of treating a nitrile with a nitrile hydratase enzyme preparation in an aqueous medium wherein the nitrile hydratase enzyme preparation is either purified enzyme or cells of microorganisms belonging to *Dietzia*. Some claims are further drawn

to the use of microorganisms belonging to *Dietzia sp., Dietzia maris*, and/or *Dietzia natronolimnaious* strain NCIMB 41165.

The references by Yamada et al. and by Nagasawa et al. (entire document including pages 1244-1248) teach microbial production of chemicals and disclose methods for production of ethylenically unsaturated amides by converting the corresponding acrilonitrile or "(meth)acrylonitrile" with microbial enzymes having nitrile hydratase activity wherein the methods encompass either the use of pure enzyme catalysts (Yamada et al) or the use of microbial cells belonging to various genera and species (Nagasawa et al). The cited references are silent about enzymatic activity of *Dietzia.*

However, the cited patents US 6,562,603(Bramucci et al) and US 6,916,638 (Aoki et al) demonstrate that the cells of microorganisms belonging to *Dietzia* including *Dietzia sp.* and/or *Dietzia maris* have nitrile hydratase activity and they are used for conversion of nitriles to corresponding amides.

For example: US 6,562,603 (Bramucci et al) discloses a method for producing ethylenicaly unsaturated amide wherein the method comprises active step of treating a nitrile with a nitrile hydratase enzyme in an aqueous medium wherein the nitrile hydratase enzyme is in a form of whole microbial cells belonging to *Dietzia sp.* (see entire document, especially, col.18, lines 11-26).

For example: US 6,916,638(Aoki et al) discloses (see entire document, especially, col. 36, example 6) a method for producing amide wherein the method comprises active step of treating a "nitrile" or glycinonitrile with a nitrile hydratase enzyme in an aqueous medium wherein the nitrile hydratase enzyme is in a form of whole microbial cells belonging to

Rhodococcus maris or *Dietzia maris* (same microorganisms in light of Rainey et al, see title, for example.).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute enzymes or cells with nitrile hydratase activity obtained from the cultures of *Dietzia* including *Dietzia sp.* and/or *Dietzia maris* of US 6,562,603(Bramucci et al) and US 6,916,638 (Aoki et al) for the enzymes or cells with nitrile hydratase activity in the methods of Yamada et al. and/or by Nagasawa et al. with a reasonable expectation of success in producing ethylenically unsaturated amides because methods for producing ethylenically unsaturated amides with microbial nitrile hydratases have been know and practiced and because representatives of the microbial genus of *Dietzia* have been known and used for their nitrile hydratase activity for the same purpose of converting nitriles into amides as adequately demonstrated by the cited references.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 1/09/2009 have been fully considered but they are not all found persuasive.

Deposit requirement for strain *Dietzia natronolimnaious* NCIMB 41165 has been met in the papers filed 1/07/2009.

Claim rejection under 35 U.S.C. 102(b) as being anticipated by Yamada et al. (IDS reference; Biosci. Biotech. Biochem., 1996, 60(9):1391-1400) has been withdrawn because the cited method does not comprise the use of enzyme in a form of whole microbial cells.

Claim rejection under 35 U.S.C. 102(e) as being anticipated by US 6,562,603 (Bramucci et al) or by US 6,916,638(Aoki et al) has been withdrawn because the cited method does not comprise the use of cells of the particular microbial species belonging to the microbial genus of *Dietzia.*

With regard to the claim rejection under 35 USC § 103 applicants argue that the cited references fail to teach the use of specific microbial species belonging to the microbial genus of *Dietzia.* This argument is not found particularly convincing because the prior art demonstrates that the cells of microorganisms belonging to the microbial genus of *Dietzia* including various microbial species of *Dietzia sp.* and/or *Dietzia maris* (same as *Rhodococcus maris*) have nitrilase activity and they are used for conversion of nitriles to corresponding amides {US 6,562,603 (Bramucci et al), US 6,916,638(Aoki et al)}. Thus, one of skill in the art would have recognized the representatives of the genus of *Dietzia* as a source of nitrilase enzymatic activity. Moreover, nitrilase activity is not a unique feature of one and only microbial genus and other related genera, for example: *Rhodococcus*, also have nitrilase activity (Nagasawa et al). Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Applicants also argue that the cited references US 6,562,603 (Bramucci et al) or by US 6,916,638(Aoki et al) teach conversion of nitriles to corresponding acids and they fail to teach production or formation of amides from nitriles. This argument is not found true because US

6,562,603 (Bramucci et al) clearly states that the microbial enzymatic complex comprises nitrilase and nitrile hydratase and that amides are converted from nitriles during first stage of the whole enzymatic process (col. 5, lines 25-35).

Thus, the claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Claim 8 is free from prior art but objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

April 22, 2009

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/
Primary Examiner, Art Unit 1657